DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2015

InvisionHeart Inc.
% Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
P.O. Box 3018
Nederland, Colorado 80466

Re: K143436
Trade/Device Name: InvisionECG System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 16, 2015
Received: April 20, 2015

Dear Thomas Kroenke,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K143436
Device Name:	InvisionECG System
Indications for Use:	The InvisionECG System is intended to acquire, display and record electrocardiographic information from adult and pediatric patients. The InvisionECG System is intended to be used in a clinical or home environment by trained healthcare professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submission Date:	20 May 2015
Submitter:	InvisionHeart Inc. 121 17th Avenue South Nashville, TN 37203
Submitter Correspondent	Mr. Michael Wurst Phone: +1 (615) 943-4926 Email: michael.wurst@invisionheart.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	InvisionHeart Inc. 121 17th Avenue South Nashville, TN 37203
Trade Name:	InvisionHeart InvisionECG System
Common and Classification Name:	Electrocardiograph
Classification Regulation:	21 CFR §870.2340
Product Code:	DPS

Substantially Equivalent Devices:	*New InvisionHeart Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	InvisionHeart InvisionECG System	K103640	Midmark Diagnostics Group / Midmark IQecg

510(k) Summary

Device Description: The InvisionECG System is a hand-held, battery powered, 12 lead electrocardiograph (ECG) system. The InvisionECG System acquires ECG information via a patient-attached lead set, and processes and transmits the ECG information to a mobile device where the ECG waveform may be viewed in near real-time. A 12 second snapshot of the waveform can be acquired, and then uploaded to an medical device data system (MDDS) from where these records can be retrieved and analyzed by trained medical professionals. Patient data is also transmitted with the ECG waveform.

The primary functions of the InvisionECG System are to:

- Acquire ECG signals from the patient's body and display the near real-time ECG waveform.

  The displayed waveform is intended to provide the bedside care provider with a preliminary view of the ECG and additional opportunity to control the quality of captured ECGs.
- Capture a 12-second ECG waveform.
- Associate the captured ECG waveform to the patient.
- Forward captured ECG waveform to an MDDS for later retrieval, analysis and diagnosis by a trained professional.

Intended Use: The InvisionECG System is intended to acquire, display and record electrocardiographic information from adult and pediatric patients.

The InvisionECG System is intended to be used in a clinical or home environment by trained healthcare professionals.

Technology Comparison: The InvisionECG System employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Intended Use	The Midmark lQecg is indicated for use, under the supervision of a Physician, to obtain electrocardiograms from the adult and pediatric human body surface. The process of taking an electrocardiogram is non-invasive, painless, without direct risk to the patient and is reproducible.	The InvisionECG System is intended to acquire, display and record electrocardiographic information from adult and pediatric patients. The InvisionECG System is intended to be used in a clinical or home environment by trained healthcare professionals.
Patient Connection	Ten (10) lead patient cable with RFI filter, defibrillator protection and patient isolation	Same

510(k) Summary

Technology Comparison (continued):

Characteristic	*Predicate Device*	*Proposed Device*
Connection to Display Device	USB or serial wired	Bluetooth wireless
ECG Analysis and Measurement	Midmark 12-lead Resting Electrocardiogram Analysis Program, personal computer (PC)-based	InvisionHeart InvisionConnect Mobile App, tablet-based
Lead Wires	AHA 12 lead wires	Same
Required Lead Wire Accessories	Electrode clips Disposable electrodes	Same
Battery Type	AA alkaline cells – serial version No batteries required for USB version	LiOn Rechargeable

Summary of Performance Testing:

Biocompatibility

The InvisionMD12, InvisionCC12, and Mobile Device have no patient contact materials, and therefore this section does not apply to them.

The InvisionLW12, electrode connector clips, and electrodes have patient contact materials and are made from medical grade biocompatible materials.

The appropriate InvisionECG system component materials were tested for biocompatibility in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Test results indicate that the appropriate InvisionECG system component materials comply with the applicable standard.

Software

The InvisionECG System contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following FDA guidance documents:

- *The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *Off-the-shelf software use in medical devices, 09 Sep 99.*
- *General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*

Test results indicate that the InvisionECG System complies with its predetermined specifications and the applicable guidance documents.

510(k) Summary

Electrical Safety

The InvisionECG System was tested for performance in accordance with the following standard:

- *ANSI/AAMI ES60601-1: 2005/(R)2012, A1:2012, C1:2009/(R)2012, A2:2010/(R)2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *ANSI/AAMI HA60601-1-11: 2011, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

Test results indicate that the InvisionECG System complies with the applicable standards.

Electromagnetic Compatibility

The InvisionECG System was tested for performance in accordance with the following standard:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicate that the InvisionECG System complies with the applicable standards.

Performance Testing – Bench

The InvisionECG System was tested for performance in accordance with internal requirements and the following standards:

- *ANSI/AAMI EC53: 2013, ECG Trunk Cables and Lead Wires.*
- *IEC 60601-2-25: 2011, Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *MIL-STD-810E, Environmental Test Methods and Engineering Guidelines*
- *ISTA Procedure 2a, Partial simulation performance test procedure – Packaged-products 150 lb (68 kg) or less.*

Test results indicate that the InvisionECG System complies with its predetermined specifications and the applicable standards.

510(k) Summary

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the InvisionECG System. The results of these activities demonstrate that the InvisionECG System is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the InvisionECG System is considered substantially equivalent to the predicate device.